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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,256	08/27/2001	Sek Chuen Chow	GJE-73	2484

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EXAMINER

WARE, DEBORAH K

ART UNIT PAPER NUMBER

1651

DATE MAILED: 09/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/889,256	Applicant(s) Chow et al.
Examiner Deborah Ware	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM

THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Jul 1, 2002

2b) This action is non-final.

2a) This action is FINAL.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1, 3, and 6-9 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1, 3, and 6-9 is/are rejected.

7) Claim(s) 3 and 8 is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO 413) Paper No(s) _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

6) Other: _____

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Claims 1, 3 and 6-9 are presented for favorable reconsideration on the merits.

The amendment filed July 1, 2002, has been received and entered.

It is noted that as an initial matter Applicants direct the examiner to attached references cited in an IDS (Information Disclosure Statement) filed October 15, 2001 of which were not previously available for her review. However, if these attachments as cited on the enclosed PTO-892 Form are not the ones Applicants have attached then Applicants should desire to phone the examiner to arrange to have such documents faxed to her computer fax so that such references may be considered. Further, the examiner requests that Applicants provide a copy of the IDS filed October 15, 2001, as the copy for the instant case before the PTO does not appear to be in the case.

Claim 8 is objected to in that there appears to be an inadvertent typo by the absence of the phrase "an excretory product" as appearing in claim 6 for a method of treating cancer wherein the same phrase is inadvertently omitted from claim 8 and should be placed before "isolatable" in claim 8 on line 2.

1. Claim 3 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the

claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103[©] and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1 and 3 and 8-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over newly cited WO 95/12615.

Claims are drawn to compositions comprising a carrier or a pharmaceutically acceptable diluent, and an excretory-secretory product, isolatable from *Necator americanus*. The

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compositions capable of inducing apoptosis in reactive T-cells. Also a method for treating inflammation is claimed.

WO 95/12615 teaches compositions comprising a carrier or a pharmaceutically acceptable diluent, and an excretory-secretory product, isolatable from *Necator americanus*. See the abstract and page 2, lines 5-8. Treating thrombosis is disclosed. Note page 1, lines 1-10.

The claims are identical to the newly cited disclosure and thus, are considered to be anticipated by the teachings therein. The capability of inducing apoptosis in reactive T-cells is an inherent feature of the product. Further, treatment of inflammation is also an inherent feature of the products. However, in the alternative that the products are different as claimed due to some unidentified claimed characteristic which is not taught by the cited reference then the claims are rendered alternatively *prima facie* obvious over the cited reference. In the alternative that there is some difference then one of ordinary skill in the art would have been motivated to provide for the compositions with the expectation of successful results for inducing apoptosis in reactive T-cells since the products are derived from hook worms and these are well known in the art to be useful for treating thrombosis and hence inflammation as thrombosis is well known in the art to induce inflammation of tissues. When cells are inhibited they can die off and as a result inflammation is decreased. The claims are at least *prima facie* obvious.

4. Claims 1, 3 and 8-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over new cited Brophy et al..

Claims are discussed above.

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Brophy teaches excretory-secretory products isolatable from Necator americanus. Note page 1, lines 1-10 and the abstract. Also note page 260, lines 1-10 of first full paragraph of which continues to page 261. Also note page 262, last paragraph, all lines. Brophy clearly teach that the products can be used to treat inflammations.

Claims are identical to the teachings of the cited Brophy reference and thus are anticipated by the reference. The capability of the compositions to induce apoptosis in T-cells is an inherent property of the composition. However, in the alternative that there is some characteristic which has not been clearly identified in the claims for which to make the reference differ somewhat from the claims then this difference is considered to be so slight as to render the claims prima facie obvious. The property of apoptosis is an inherent property of the composition as there is no difference in how the compositions are prepared. The disclosed method of preparation of the disclosed compositions is so similar to the claimed compositions, thus, the compositions are the same and would have the same properties, or alternatively would have been expected to provide for the same properties. Thus, the claims are at least prima facie obvious.

5. Claims 1, 3 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/12615 and Brophy et al, both cited above, in view of Kalinkovich et al.

The claims are discussed above as are the WO patent and Brophy et al. Kalinkovich teaches T-cell apoptosis is related to Necator americanus infection of mammals, humans specifically. Note page 419, all lines.

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The claims differ from the cited disclosures of WO Patent and Brophy et al. in that cell apoptosis is not specifically disclosed. Although it is believed that this is an inherent property this rejection is made to supplement the alternative 103 portions of the above rejections.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for the compositions and method of treating inflammation in a human using the compositions as disclosed by WO Patent and Brophy with the expectation that T-cell apoptosis would be induced since Kalinkovich et al. clearly teach that during helminth infection T-cell apoptosis was observed. Therefore, one of skill in the art would have expected successful results for the capability of the compositions to induce T-cell apoptosis as the same as been observed in the cited prior art as evidenced by Kalinkovich. The claims are deemed at least prima facie obvious.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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6. Claims 1, 3 and 6-9 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over newly cited Vlasuk et al.

7. In addition to as discussed above, the claims are also drawn to a method for treating cancer.

8. Vlasuk et al. teach a composition comprising the excretory-secretory product isolatable from Necator americanus and further teach that such compositions can be administered for treating infections and cancer. Note column 37-38 all lines and column 3, 65-66.

9. The claims are identical to the cited disclosure and are therefore, considered to be anticipated by the teachings of Vlasuk. However, in the alternative that there is some unidentified claimed characteristic for which to provide a difference between the claims and the cited disclosure then the difference is considered to be so slight as to render the claims obvious. The induction of apoptosis of T-cells is considered to be an inherent trait of the NAP disclosed by Vlasuk. Also the reference teaches that cancer can be treated of which is known to be not subjected to apoptosis but a cancer cell is immortal when left untreated. Therefore, especially since cancer is disclosed to be treatable then T-cell apoptosis is considered to be an inherent property of the NAP (Nematode Extracted Protein). Thus, since cancer can be treated with the NAP, cell death (apoptosis) must be induced by the NAP. However, in the alternative that cell apoptosis induction is not an inherent property then the claims are rendered *prima facie* obvious over the cited disclosure and the claims would have been expected to be capable of successful T-

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cell apoptosis as the same is at least suggested, if not taught, by the cited reference. Claims are at least *prima facie* obvious in the alternative over this newly cited reference.

10. Claims 1, 3 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vlasuk et al. in view of Kalinokovich et al., both discussed above.

Claims are discussed above.

Claims differ, if at all, from Vlasuk in that cell apoptosis is not specifically disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was filed to combine the cited disclosures in order to provide for a composition and methods, therefore, with the successful expectation that T-cell apoptosis would be induced by such compositions. Clearly one of skill would have been motivated to provide for these compositions based upon the teachings of the cited prior art. Each of the claimed features are clearly disclosed herein. One of skill would have expected successful results for treating inflammation and cancer in a human being using the compositions disclosed by Vlasuk. Cell apoptosis is clearly disclosed by Kalinokovich to be associated and related to *Necator americanus*. Thus, one of skill in the art would have expected that its isolatable products would have the same inherent features as the hookworm from whence it was derived therefrom. Thus, the claims are at least clearly *prima facie* obvious over the cited prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Deborah K. Ware

September 30, 2002


DAVID M. NAFF
PRIMARY EXAMINER
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